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10/517,451	12/09/2004	Ryuzo Ueno	1691-0205PUS1	5585
2292 7590 04/14/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
LAU, JONATHAN S				
ART UNIT		PAPER NUMBER		
1623				
NOTIFICATION DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/517,451

**Applicant(s)**

UENO ET AL.

**Examiner**

Jonathan S. Lau

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3 and 5-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 5-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is responsive to Applicant's Amendment and Remarks, filed 19 Dec 2007, in which claims 2 and 4 have been canceled, claims 1, 3 and 5 have been amended to change to scope and breadth of the claims, and claims 7 and 8 have been added.

This application is the national stage entry of PCT/JP03/07613, filed 16 Jun 2003; and claims benefit of foreign priority document JAPAN 2002-178319, filed 19 Jun 2002; the certified copy of the priority document is in Japanese and no English translation has been filed.

Claims 1, 3 and 5-8 are pending in the current application. Amended claims 1, 3 and 5 have been amended to change to scope and breadth of the claims. New claims 7 and 8 have been added.

### ***Rejections Withdrawn***

Applicant's remarks, filed 19 Dec 2007, with respect to the rejection of claims 1-6 under 35 U.S.C. 112, second paragraph have been fully considered and are not found to be persuasive. However, the ordinary definition of solution (definition of solution, Dictionary.com, cited in PTO-892) encompasses, a "homogeneous mixture of two or more substances, which may be solids, liquids, gases, or a combination of these." Therefore a homogeneous mixture of water and maltitol, such as in the form of a solid seed crystal, would be interpreted by one of ordinary skill in the art as a solid aqueous

solution of maltitol, and based on the definition now of record Examiner finds that such a term is not indefinite. Further, Applicant remarks that “the maltitol aqueous solution having a solid content of 70 to 90% (first maltitol aqueous solution) is liquid at 90 to 120 °C, and the maltitol aqueous solution having a solid content of 97.5 to 99.5% (second maltitol aqueous solution) is liquid at 120-140 °C. The maltitol aqueous solution is always supplied in a liquid form.” However, the melting point of maltitol is 145 °C, and a maltitol aqueous solution of 99.5% maltitol and ergo 0.5% water (melting point 0 °C) would, due to the high concentration of maltitol, approach ideal solution behavior. 99.5 wt% maltitol and 0.5 wt% water, is approximately 0.289 mol maltitol and 0.027 mol water, or 91.5 mol% maltitol, and would have a melting point of  $0.915 \times 145 \text{ °C} + 0.01 \times 0 \text{ °C} \approx 133 \text{ °C}$ . This melting temperature is within the recited temperature range of 120-140 °C, and therefore said maltitol aqueous solution is not necessarily supplied in liquid form as asserted in Applicant’s remarks. Absent data supporting the assertion that the maltitol aqueous solutions are necessarily liquid at the specified temperature, Applicant’s claims to a “maltitol aqueous solution” are understood to encompass maltitol aqueous solutions in the solid physical state of matter based on the ordinary definition of a solution now of record.

The rejection of claims 1-6 has been **withdrawn**.

Applicant’s amendment, filed 19 Dec 2007, with respect to the rejection of claim 5 under 35 U.S.C. 112, second paragraph has been fully considered and is found to be

persuasive because claim 5 has been amended to specify how many times water is added and how much water is added.

The rejection of claim 5 has been **withdrawn**.

Applicant's amendment, filed 19 Dec 2007, with respect to the rejection of claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over Kawashima et al. (U.S. Patent No. 5,354,856; of record) in view of Flickinger et. al. (Encyclopedia of bioprocess technology - Fermentation, biocatalysis, and bioseparation, Pages 1259-1260; of record) has been fully considered and is found to be persuasive because independent claims 1 and 3 amended to change to scope and breadth of the claims by the recitation of the specific temperature ranges 90 to 120 °C and 120 to 140 °C.

The rejection of claims 1-6 has been **withdrawn**.

The following new grounds of rejection have been necessitated by Applicant's amendment, filed 19 Dec 2007, in which claims 1, 3 and 5 have been amended to change to scope and breadth of the claims, and claims 7 and 8 have been added.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 1, 3, 5 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al. (US Patent 5,304,388, issued 19 Apr 1994, cited in PTO-892).

Ueno et al. discloses a method of manufacturing a powdery crystalline maltitol in which comprises adding seed crystals of maltitol at a temperature lower than the melting point of the seed crystals of maltitol to an aqueous solution of maltitol with 1-15% by weight of moisture content; kneading the mixture and continuously applying a shearing force to the kneaded mass, said aqueous solution of maltitol containing not less than 85% by weight maltitol and having a temperature higher than 100 °C (column 2, lines 23-49), meeting the limitations of the first maltitol aqueous solution of instant claim 1 and the maltitol aqueous solution of instant claim 3. Ueno et al. discloses the addition of seed crystals of maltitol added during agitation at a temperature lower than 140 °C, said seed crystal having a purity of higher than 80% by weight and a moisture

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content of preferably not more than 5% by weight (spanning column 3, lines 65-68 and column 4, lines 1-20), meeting the limitations of the second maltitol aqueous solution of instant claim 1 and the temperature of the maltitol aqueous solution of instant claim 3. Ueno et al. discloses it is well known in the art that the method involves gradual cooling so as to solidify the maltitol and powderized, or pulverized (column 1, lines 45-50), meeting the limitations of instant claim 1 and 3. The seed crystal added contains not more than 10% by weight moisture and can be 50% by weight of the total amount of maltitol (column 4, lines 16-19), equivalent to the addition of water in the amount of 5 parts by weight based on 100 parts by weight of the maltitol aqueous solution, meeting the limitations of instant claim 5. Ueno et al. provides guidance for this moisture by disclosing "It is essential that raw maltitol to be crystallized contain moisture, which is an essential condition of the present invention." (column 2, lines 52-54) The kneader is a continuous-type mixer (column 4, lines 40-41) which has a temperature-controlling jacket (column 4, lines 65-66), or cooler, meeting the limitations of instant claim 6.

Ueno et al. does not specifically disclose the method wherein the second maltitol aqueous solution has a solid content of 97.5 to 99.5 wt% maltitol (instant claim 1). Ueno et al. does not specifically disclose the method wherein the maltitol aqueous solution has a solid content of 97.5 to 99.5 wt% maltitol (instant claim 3), for clarity referred to as the "first" maltitol aqueous solution.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the method disclosed by Ueno et al. wherein the second maltitol aqueous solution, or seed crystal, has a solid content of 97.5 to 99.5 wt% maltitol, or

wherein the "first" maltitol aqueous solution has a solid content of 97.5 to 99.5 wt% maltitol. Ueno et al. provides motivation to practice the invention with a seed crystal that has a solid content of 97.5 to 99.5 wt% maltitol by teaching, "the seed crystals of maltitol, which contain a high content of anhydrous crystalline maltitol, are ordinarily required to have a purity of higher than 80% by weight..." (column 4, lines 7-10). Ueno et al. discloses the "first" maltitol aqueous solution containing not less than 85% by weight maltitol, and teaches embodiments wherein the "first" maltitol aqueous solution contains 92% maltitol (column 4, line 63). The teaching of this embodiment would motivate one of ordinary skill in the art to practice the invention disclosed by Ueno et al. wherein the "first" maltitol aqueous solution has a solid content of 97.5 to 99.5 wt% maltitol. See also MPEP 2144.05 I., "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)"

**Response to Remarks:**

Applicant remarks that claims 1 and 3 are drawn to different inventions. However, because the open language of "comprising the steps of" does not limit the invention to only the disclosed steps and nothing more, the invention disclosed by Ueno et al. reads upon both claims 1 and 3. As detailed above, the "aqueous solution of maltitol" disclosed by Ueno et al. reads upon both the "first maltitol aqueous solution" of instant claim 1 and the "maltitol aqueous solution" of instant claim 3. The "seed crystal"



disclosed by Ueno et al. reads upon both the "second maltitol aqueous solution" of instant claim 1 and the added water of instant claim 3.

As recited above in the withdrawal of the rejection of claims 1-6 under USC 112, second paragraph, the "seed crystal" disclosed by Ueno et al. reads upon the "second maltitol aqueous solution".

Amended claims 1, 3, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al. (US Patent 5,304,388, issued 19 Apr 1994, cited in PTO-892) in view of Nurmi et al. (WIPO Publication WO 02/04473, published 17 Jan 2002, cited in PTO-892).

Ueno et al. discloses as above.

Ueno et al. does not specifically disclose the process wherein the crystalline maltitol is produced without using seed crystals.

Nurmi et al. teaches a method of crystallizing maltitol from a maltitol solution. Nurmi et al. teaches that to form maltitol crystals from a supersaturated solution, seeding is employed (page 5, lines 7-8) and that "Seeding may also be carried out using any other known seeding methods, without adding maltitol seed crystals. Seeding may be effected using spontaneous seeding or ultrawave seeding, for example." (page 5, lines 14-16). Nurmi et al. teaches "In one embodiment of the invention, additional feed liquid is added to the maltitol solution simultaneously with the crystallization by evaporation in order to raise the level of the maltitol solution in the crystallizer and to raise the dry substance content of the maltitol solution." (page 6, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the invention of Ueno et al. without using seed crystals as taught by Nurmi et al. Nurmi et al. teaches that "Seeding may also be carried out using any other known seeding methods, without adding maltitol seed crystals." This equivalency is therefore recognized in the prior art, and it is *prima facie* obvious to substitute one equivalent process for another. See also MPEP 2144.06 II., "An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)." Nurmi et al. does not destroy the feature of Ueno et al. of adding a second maltitol aqueous solution containing moisture because Nurmi et al. teaches "additional feed liquid is added to the maltitol solution simultaneously with the crystallization by evaporation in order to raise the level of the maltitol solution in the crystallizer," or maintaining the amount of water moisture, "and to raise the dry substance content of the maltitol solution," or adding a second maltitol aqueous solution.

### ***Conclusion***

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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